REMARKS

Claims 2-24 are now in the case.

Claim 1 has been canceled.

Claims 13-20 have been withdrawn from further consideration.

Claims 2, 3, 5, 6 and 23 are rejected.

Claims 4, 7-12, 21-22 and 24 are objected to.

No Claim has been allowed.

The Amendments.

Method Claim 13 has been rewritten to include all the limitations of base Claim 2.

The Rejection under 35 U.S.C. §102(b), Top Foods.

Claims 2, 3, 5, 6 and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by Top Foods. Withdrawal of this rejection is requested for the following reasons advanced in Applicants' previous response.

Top Foods teaches a transfer sheet for transferring an image from a water-soluble edible film to the surface of a food containing moisture. Although the English abstract speaks of starch of devil's tongue as being "dissolved" in a liquid such as

water, there is no indication of a treatment that would result in solubilization of starch. Applicants have made it clear in their own disclosure that dissolution of starch occurs only under very severe treatment conditions, such as those inherent in excess steam jet cooking (page 8 of specification). Likewise the requirements of high temperatures and shear to solubilize starch are discussed in Eskins et al. (U.S. Patent No. 5,882, 713, col. 9, lines 25 *et seq.*; and in R. E. Klem and D. A. Brogly, (*Pulp and Paper*, **55**: 98-103, 1981). No such treatment is taught by Top Foods.

Insight into the disparity between the teachings of the Top Foods abstract and the conventional knowledge in the literature is provided by the machine translation kindly supplied by the Examiner in the subject Office Action. The water-soluble, coating film of Top Foods is NOT STARCH at all, but rather is a hydrocolloidal polysaccharide akin to pectin. It is clear from the English abstract and also from the machine translation, that the source of this polysaccharide is devil's tongue, also described in the translation as "konnyaku". Submitted herewith are two Internet references (konnyaku.com and PDR health), the former of which describes konnyaku as alkali-treated konjac flour consisting mainly of glucomannan. Glucomannan is further

described in PDR health as a polysaccharide comprised of approximately 60% D-mannose and 40% D-glucose bonded together by β-1,4 linkages. In contrast, starch is a polysaccharide composed of repeating 1,4-α-D-glucopyranosyl units (anyhydroglucose units). Konnyaku.com describes the konjac flour as being a soluble dietary fiber (that is, not digestible in the human system), whereas starch in its native state is an insoluble polysaccharide that is digestible by amylase in the human system. Thus, both the chemical structures and functional properties of starch and konnyaku are completely different. This would explain why the coating of Top Foods is not firmly attached to the plastic film and is transferrable to the food product, whereas the Applicants' starch coating is adherent to the polymeric substrate. In conclusion, one reading the Top Foods abstract in light of the literature would recognize that the term "starch" as applied to konnyaku is a misnomer, and probably no more than an unfortunate result of an abstracting or translation error.

Allowable Subject Matter.

Applicants note that Claims 4, 7-12, 21, 22 and 24 have been objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all

of the limitations of the base claim and any intervening claims. Given that the base Claim 2 should now be allowable in view of the arguments advanced above, the objection is deemed to be obviated and these claims are considered allowable in their present form.

Status of Process Claims 13-20.

The Examiner has indicated that method Claims 13-20, previously withdrawn from consideration pursuant to an election, will be rejoined with the product claims upon allowance of the product claims and recitation of all the limitations of the independent product claim. Accordingly, the present amendment serves to render the process claims of commensurate scope to independent Claim 2, which is now considered to be in condition for allowance.

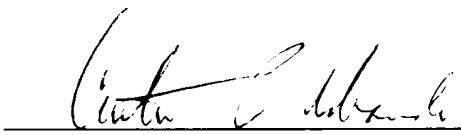
Summary.

Insofar as the rejection over Top Foods was the only remaining issue of patentability in the case, and insofar as the relevancy of the teachings of Top Foods to the claimed invention has been dispelled, all the product claims presented for

examination as well as the previously withdrawn method of making claims are deemed to be in condition for allowance. No new claims or issues have been raised, and the amendments submitted herewith have been at the invitation of the Examiner to permit rejoinder and allowability of the method claims.

Accordingly, a favorable action on the merits of Claims 2-24 is earnestly solicited.

Respectfully submitted,



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Enclosures
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What's Konjac Flour

Konjac flour is obtained from the tubers of various species of Amorphophallus.It is a soluble dietary fiber that is similar to pectin in structure and function.

konjac flour consists mainly of a hydrocolloidal polysaccharide, glucomannan. Glucomannan is composed of glucose and mannose subunits :inked with B-1 ,4 linkage at a molar ratio of i .O:1 .6. It is a slightly branched polysaccharide having a molecular weight of 200,000 to 2,000,000 daltons. Acetyl groups along the glucomannan backbone contribute to solubility properties and are located, on average. every 9 to 19 sugar units. In general, the konjac tuber is ground and milled, and its impurities are separated by either mechanical separation, water Wash, or aqueous ethanol wash to produce konjac flour. All processes are similar and result in a flour that is enriched in glucomannan and meets the specification listed in the Food Chemicals Codex.

konjac flour has a long history of safe use. The first documented use of konjac tuber as a source of food In China and Japan was In the ancient Japanese written work entitled, "Man-you-shuu." which was edited In the sixth century AD. A comprehensive collection of historical materials, which reference konjac in novels, essays and poems, was published by the Japanese Konjac Society in April 1985. The collection of materials document that its use as food is deeply rooted in the lives and customs of the people in Japan and China for centuries, Historical[y, konnyaku, the alkali•treated konjac flour, was used to cleanse one's digestive tract of irritating and poisonous substances and keep one's internal organs clean. The konjac tuber was introduced into Hawaii in 1858 and konnyaku was commonly eaten as food once or twice a week by Japanese in Hawaii. Assuming a worse-case estimate of consumption for konnyaku once a week for eaters only, the estimated consumption of konnyaku as a food is 20 g/day.

The *Food Chemicals Codex* lists the current uses of konjac flour in the United States as a gelling agent, thickener, film former, emulsifier. and stabilizer. Assuming that konjac flour would replace all uses of pectin, modified pectin, and gelatin. a worse case estimate for konjac flour consumption as a food ingredient In finished foods would be I .2 g/person/day. However, because use of konjac flour is self limiting and would not substitute for all uses of pectin and gelatin,a more reasonable estimate would be that konjac flour would substitute for one third of the uses and, thus. would be consumed at a level of about 0.4 g/person/day.

The major component of konjac flour. Feeding studies with rats and dogs indicate that the no-observed effect level for glucomannan was 2.5%of the diet. There are several studies which deal with the effects of glucomannan on aspects of the biochemical dynamics of cholesterol, triglyceride, phospholipid, bile acid, glucose and insulin in the,e.experimental animals, While none of these studies can be called a safety study, they provide, some information on the safety of glucomannan in that they do not mention any adverse toxicological effects associated with the administration or glucomannan. These studies, in total, demonstrate that

glucomannan has the ability to lower serum cholesterol levels and to delay glucose absorption.

Studies using glucomannan have been tested on humans, principally to study its influence on cholesterol and glucose absorption from the gastrointestinal tract. These studies indicate that glucomannan has the ability to lower serum cholesterol and may lower serum triglyceride and bile acid level as well. Glucomannan may also have an influence on glucose tolerance and glucose absorption. These findings have also been seen in the animal studies, mentioned above. While these studies cannot be deemed to be human safety studies they do indicate that no adverse toxicological effects were associated with the administration of glucomannan.

In addition, the results from several in vitro iron absorption studies demonstrate that glucomannan, the major component of konjac flour, does not bind iron.

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Glucomannan

DESCRIPTION

Glucomannan is a hydrocolloidal polysaccharide comprised of D-glucose and D-mannose residues (hence, the name) bonded together in beta-1,4 linkages. Approximately 60% of the polysaccharide is made up of D-mannose and approximately 40%, of D-glucose. Some of the sugar residues in glucomannan are acetylated. The molecular weight of this slightly branched polysaccharide ranges from 200 kilodaltons to 2,000 kilodaltons.

Glucomannan, which is also classified as a soluble dietary fiber, is derived from konjac flour. Konjac flour itself is derived from the *Amorphophallus* species, plants which are related to the common philodendron house plant and which grow in only certain parts of the world, including some regions in China and Japan. One member of the *Amorphophallus* genus called *Amorphophallus konjac*, is also known as voodoo lilly, devil's tongue and konjac. Konjac flour, however is derived from the tubers of various species of *Amorphophallus*, and the term konjac is used generically for the various species, as well as for the flour from their tubers. In addition to being known as konjac, the plant is called ju ruo (pronounced in Chinese) by the Chinese people, and called konjaku or konnyaku by the Japanese.

Konjac flour has a long history of use in both China and Japan as a food substance and as a folk remedy. Glucomannan products are widely used in Japan and China as general health aids, topically, for skin care and as a thickening agent for foods, among other things. Glucomannan, sometimes called konjac mannan, is marketed in the United States as a dietary supplement. Polysaccharides containing D-mannose and D-glucose in similar proportions to that found in konjac flour are found in other organisms, such as certain yeasts. Yeast glucomannan is not marketed as a dietary supplement.

ACTIONS AND PHARMACOLOGY

ACTIONS

Glucomannan may have laxative activity. It may also have activity in the control of serum glucose and lipid levels. Glucomannan has putative bariatric activity.

MECHANISM OF ACTION

The laxative effect of glucomannan is thought to be due to the swelling of glucomannan with consequent increase in stool bulk.

Some studies indicate that glucomannan may improve glycemic control in Type 2 diabetics. The mechanism of this effect is unclear. Glucomannan may delay the absorption of carbohydrates by increasing gastric-emptying time and/or decreasing small intestinal transit time.

The mechanism of glucomannan's possible hypocholesterolemic activity is likewise, unclear. The polysaccharide may stimulate the conversion of cholesterol to bile acids, as well as the fecal excretion of bile acids. Glucomannan may also decrease the intestinal absorption of cholesterol.

The putative bariatric (weight reduction) effect of glucomannan is not well understood. The swelling of glucomannan that occurs when it absorbs water in the gastrointestinal tract, may confer a feeling of satiety in some.

PHARMACOKINETICS

Following ingestion of glucomannan, very little of it is digested in the small intestine. Glucomannan is resistant to hydrolysis by the digestive enzymes. Significant degradation occurs in the large intestine via the action of colonic bacteria. Products of degradation in the large intestine, include formic acid, acetic acid, butyric acid, propionic acid,

beta-1,4- D-mannobiose (4-O-beta-D-mannopyranosyl-D-mannopyranose), cellobiose(4-O-beta-D-glucopyranosyl-D-glucopyranose), 4-O-beta-D-glucopyr-anosyl-D-mannopyranose, glu- cose and mannose. There may be some absorption of these degradation products from the large intestine. Most of them are excreted in the feces, along with unchanged glucomannan. Butyrate is used as a respiratory fuel by the colonocytes.

INDICATIONS AND USAGE

INDICATIONS

Glucomannan has demonstrated some usefulness in the management of obesity, diabetes and constipation. It has some favorable effects on lipids.

RESEARCH SUMMARY

Some studies have demonstrated that glucomannan has some efficacy in the management of obesity. In an eight-week, double-blind study, 20 obese subjects received 1 gram of glucomannan or placebo daily. Subjects were instructed not to change eating or exercise habits. Glucomannan-supplemented subjects had a significant mean weight loss of 5.5 pounds. Serum cholesterol and LDL cholesterol were significantly reduced, as well, in the treated group.

In a double-blind trial, this one involving 60 children under age 15 with childhood obesity, there was a significant reduction in weight in both treated and placebo groups. Further, there was a concommitant significant reduction in alpha-lipoprotein and an increase in triglycerides in the treated group but not in the placebo group. However, in another controlled study of childhood obesity, excess weight and triglycerides were significantly decreased in treated subjects but not in controls.

In a 3-month study of severely obese patients, a hypocaloric diet therapy by itself was tested against the same hypocaloric diet in combination with 4 grams of glucomannan (in three doses) daily. The combination therapy resulted in more significant weight loss in relation to fatty mass alone, in an overall improvement in lipid status and carbohydrate tolerance and a greater adherence to the diet. The researchers concluded: "Due to the marked ability to satiate patients and the positive metabolic effects, glucomannan diet supplements have been found to be particularly efficacious and well tolerated even in the long-term treatment of severe obesity."

Glucomannan, given in a long-term feeding program to baboons, showed beneficial effects on glucose homeostasis. Subsequently, it was shown that 2.6-grams and 5.2-grams daily doses of glucomannan, added to a carbohydrate rich breakfast in eight patients with previous gastric surgery, improved their reactive hypoglycemia and decreased the postprandial rise in plasma insulin. Benefits were achieved without unpalatability and carbohydrate malabsorption.

In a recent randomized, placebo-controlled metabolic trial, glucomannan was found to improve metabolic control in high-risk Type 2 diabetic patients, as measured by glucose and lipid levels and blood pressure. More research is warranted.

Several studies have demonstrated that glucomannan is an effective treatment for many with chronic constipation. This has been demonstrated in double-blind, placebo-controlled and multicenter studies. One to 4 grams daily, in divided doses, are typically used in these studies of constipation.

CONTRAINDICATIONS, PRECAUTIONS, ADVERSE REACTIONS

CONTRAINDICATIONS

Glucomannan is contraindicated in those hypersensitive to any component of a glucomannan-containing product. It is also contraindicated in those with intestinal obstruction, difficulty in swallowing and esophageal narrowing.

PRECAUTIONS

Pregnant women and nursing mothers should avoid glucomannan supplements.

Glucomannan must be taken with adequate amounts of fluids. Inadequate fluid intake may cause glucomannan to swell and block the throat, esophagus or intestines.

Tablet forms of glucomannan should be avoided.

Glucomannan should not be taken before going to bed.

Type 2 diabetics who use glucomannan, may require adjustment of their antidiabetic medications.

ADVERSE REACTIONS

A few cases of esophageal obstruction have been reported with the use of glucomannan tablets. The most common adverse reactions are flatulence and abdominal distension. Diarrhea is occasionally reported.

INTERACTIONS

NUTRITIONAL SUPPLEMENTS

Fat-soluble vitamins (A, D, E, K): Concomitant intake of fat soluble vitamins and glucomannan may decrease the absorption of the fat-soluble vitamins.

FOODS

Glucomannan may decrease the absorption of fat-soluble vitamins found in foods.

OVERDOSAGE

Glucomannan overdosage has not been reported.

DOSAGE AND ADMINISTRATION

Glucomannan supplements are mainly available in capsules. Glucomannan powder is also available and there are glucomannan combination products.

Doses used range from one to four grams daily, taken in divided doses and with plenty of liquids.

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